

SEP 25 2006

Reply under 37 CFR 1.116
Expedited Procedure
Technology Center 1624
Attorney Docket No. CV06039US01

REMARKS

Applicants are pleased to note that claim 13 has been indicated as allowable if rewritten in independent form and sincerely appreciate the suggestions to facilitate allowance of the application.

Claims 1-33 are pending in this application. Claims 10, 11, 27 and 28 have been withdrawn by the Examiner as being drawn to a non-elected invention. Claims 1, 14, 16, 18, 30 and 32 have been amended, without prejudice. The amendments to claims 1 and 18 are supported by original claim 1 and in the specification at page 30, lines 12 – 31. No new matter has been added to the application by any of the foregoing amendments.

Rejections Under 35 USC § 112

At pages 3-5 of the Office Action, claims 1-9, 12, 14-26 and 29-33 have been rejected under 35 USC § 112, second paragraph, for alleged indefiniteness regarding:

- (1) C₀ alkylene;
- (2) Substitution of groups such as alkyl;
- (3) -N=N=N⁺;
- (4) Meaning of the term “diabetes”;
- (5) Meaning of the term “sterol”; and
- (6) Meaning of the term “stanol”.

Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

This rejection was fully addressed in the previous Amendment filed July 7, 2006 (“First Amendment”).

Regarding item (1) above, one skilled in the art would understand that -(C₀-C₁₀ alkylene)-G, for example, means that the alkylene moiety is not present when C is zero, i.e., there is a covalent bond between the main molecule and G, i.e., -G. If C is one, then the group would be -CH₂G, for example. While Applicants respectfully disagree with the rejection, to expedite examination of the application Applicants amended claims 1 and 18 in the First Amendment to delete reference to C₀ and instead show these moieties as, for example, -G.

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Regarding item (2), while Applicants respectfully disagree with the rejection, to expedite examination Applicants amended claims 1 and 18 in the First Amendment to specify that each of the alkyl, alkenyl, alkynyl, alkylene, alkoxyalkoxy, alkoxyalkoxyalkoxy, alkoxycarbonylalkoxy, alkoxyarylalkoxy, alkoxyiminoalkyl, alkylidoyl, allyloxy, aryl, arylalkyl, aryloxy, arylalkoxy, aroyl, aroyloxy, aroylaroyloxy, arylalkoxycarbonyl, benzoylbenzoyloxy, heteroaryl, heteroarylalkyl, heteroarylalkoxy, dioxolanyl, heterocyclyl, heterocyclylalkyl, heterocyclylcarbonyl, or heterocyclylcarbonylalkoxy groups, when present, is independently substituted or unsubstituted. This amendment is supported in the description of each moiety in the specification at page 23, line 5 through page 28, line 12.

Regarding item (3), Applicants amended claims 1 and 18 in the First Amendment to clarify that the azido moiety was intended.

Regarding item (4), the meaning of the term diabetes is intended to be inclusive and is well known to those skilled in the art. While Applicants respectfully disagree with the rejection, to expedite examination Applicants amended claims 14, 16, 30 and 32 in the First Amendment to specify diabetes mellitus, as discussed at page 1, line 18 of the specification. The term "diabetes" was canceled from claims 14, 16, 30 and 32 in the present Amendment, without prejudice to filing of one or more divisional applications directed to the canceled subject matter.

Regarding item (5), the term "sterol" is explained in the specification at page 47, lines 24-26 as including cholesterol and phytosterols, such as sitosterol, campesterol, stigmasterol and avenosterol and mixtures thereof. While Applicants respectfully disagree with the rejection, to expedite examination of the application claims 14, 16, 30 and 32 were amended in the First Amendment to cholesterol and phytosterols.

Regarding item (6), the term "stanol" is explained in the specification at page 47, lines 25-27 as including 5 α -stanols, such as cholestanol, 5 α -campestanol, and 5 α -sitostanol and mixtures thereof. While Applicants respectfully disagree with the rejection, to expedite examination of the application claims 14, 16, 30 and 32 were amended in the First Amendment to 5 α -stanols.

None of the foregoing amendments were made for any prior art reasons. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

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At page 2 of the Office Action, claims 1-2, 4-9, 12, 14-19 and 21-26 have been rejected under 35 USC § 112, paragraph 1 for lack of written description, alleging that the specification does not support substituted dioxolanyl. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. Support for substituted dioxolanyl is set forth at page 27, lines 10-23 of the specification. More specifically, dioxolanyl is listed as an example of a heterocyclyl moiety at line 22. At lines 17-19, it is noted that the heterocyclyl can be optionally substituted by one or more "ring system substituents", which may be the same or different. Ring system substituents are listed at page 28, lines 1-12. These ring system substituents are as listed in claim 1.

At page 3 of the Office Action, claims 1-9, 12-19 and 21-24 have been rejected under 35 USC § 112, paragraphs 1 and 2, for lack of written description and lack of enablement for trialkylammonium alkyl radical. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. Claims 1 and 18 have been amended to clarify that this is the trialkylammonium alkyl salt. Applicants wish to point out that claims 1 and 18 include pharmaceutically acceptable salts of the compound of Formula (I). Please see page 30, lines 12 - 31 for a discussion of suitable acids for salt formation and description of formation of the salts. In view of the claim language and disclosure in the specification, one skilled in the art can readily ascertain the meaning of trialkylammonium alkyl salt. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

At pages 5-9 of the Office Action, claims 16 and 32 have been rejected under 35 USC § 112, first paragraph, for lack of written description or enablement as to the treatment of the disorders listed. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. While Applicants respectfully disagree with the rejection, to expedite examination of the application Applicants have amended claims 14, 16, 30 and 32 to delete treatment of diabetes mellitus, obesity, stroke, demyelination, Alzheimer's disease or regulating a level of an amyloid β peptide, without prejudice to the filing of one or more divisional applications directed to the canceled subject matter. These amendments were not made for any prior art reasons. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

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In view of the remarks above, reconsideration and withdrawal of the rejections, and favorable allowance of all claims is respectfully requested. Should the Examiner have any questions or wish to discuss this matter further, he is invited to contact Applicants' representative at 412-471-8815.

Respectfully submitted,

THE WEBB LAW FIRM

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